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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,376	07/01/2003	John S. Patton	0005.15	3703

21968 7590 07/03/2008

NEKTAR THERAPEUTICS
201 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
07/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/612,376	PATTON ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response dated 5-12-08 is acknowledged.

Claims included in the prosecution are 26-59.

In view of applicant's arguments, the prior art rejections are withdrawn.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 31-34 and 39-43, 46, 49-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-29, 32-33, 35-49 and 51-58 of copending Application No. 10/245,705. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 28 in the copending application are drawn to generic pharmaceutical agent in an amorphous dry powder form having the particle sizes of less than 10 microns and claims 32 and 33 identify insulin as one of the pharmaceutical agents. Claim 41 further identifies the composition is a spray dried composition; instant claims drawn specifically to insulin and in specific amounts therefore, are anticipated by the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments have been fully considered, but are not persuasive. Applicant argues that a non-statutory obviousness-type double patenting rejection of claim 31 would be appropriate only if claim 31 is ether anticipated by or would have been obvious and neither is the case here. These augments are not persuasive. Claim 28 in 705 is generic with respect to the active agent. However, the dependent claims in 705 recite insulin and therefore, it is evident that claim 28 in 705 includes insulin. Claim 28 in 705 is generic with respect to the amounts and therefore, instant amounts of insulin, that is 20 to 80%, are anticipated by the claims in 705. Furthermore, one of ordinary skill in the art would be motivated to change the amounts of insulin and the

excipient to obtain the best possible results and such changes would have been obvious to one of ordinary skill in the art. In response applicant argues that the examiner has failed to provide any support or rationale for that position. The examiner points out that the amount of an active agent administered depends on the severity of the condition to be treated. In instant case, the amount of the insulin to be administered depends upon the glucose levels in the blood and naturally if the amount of insulin is increased, the excipient amount in the composition decreases. The claims in the copending application recite not just insulin, but the carrier too. In response to applicant's arguments of unexpected results, the examiner points out that instant claims are composition claims and not method claims and the claims in the said copending application recite the same insulin composition.

3. Claims 31-34 and 39-43, 46, 49-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-43 of copending Application No. 10/245,706. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application are drawn to insulin composition in a carrier buffer in a powder form suitable for administration by inhalation. The dependent claim 32 identifies the particle sizes to be less than 10 microns. The dependent claim 28 identifies the buffer to be trehalose, lactose and other sugars. Instant claims are drawn to powdered amorphous insulin compositions with particle sizes below 10 microns and with moisture content of below 10 % containing the same carbohydrate material. The claims in the copending application thus, are generic with respect to the amounts of insulin and the

particle sizes and therefore, instant claims are anticipated by the claims in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This rejection is maintained since contrary to applicant's arguments, ***this*** double patenting ***rejection is not the only rejection*** in this application. As clearly evident, there are other double patenting rejections.

4. Claims 31-34 and 39-43, 46, 49-56 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 13-16 of U.S. Patent No. 6,358,530 in combination with Rubsamen (5,364,838). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in said patent are drawn to generic polypeptide active agent and instantly claimed insulin is a polypeptide. One of ordinary skill in the art would be motivated to use insulin as the polypeptide with a reasonable expectation of success since the reference of Rubsamen shows that insulin is administered as a powder in an aerosol form for pulmonary delivery. In the patented claims, one of the excipients claims is a carbohydrate and the dependent claim 5 identifies the carbohydrate to be lactose, trehalose and others just as in instant claims. The patented claims are generic with respect to the amount of the polypeptide and instant amounts of insulin are therefore, anticipated by the patented claims. The patented claims do not exclude the presence of buffers such as sodium citrate in instant claims.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the side by side comparison of the claims shows that applicant's claim 31 recited features that are not present in 530 patent. This argument is not persuasive since 530 is generic with respect to the therapeutic agent (instant claim 39 recites polypeptide as the active agent) and the examiner has combined it with Rubsamen to show the motivation to use insulin in 530 patent and the amounts of insulin (a polypeptide) are deemed to be manipulatable parameter since the amounts depend upon factors such as the age of the patient and severity of the disease. Applicant's arguments pertaining to the effective filing date of the present application and that of 530 are not persuasive since one of the reasons for the double patenting rejections is to tie the patents which have similar inventions together. Applicant's arguments with regard to instant claim 39 are similarly not persuasive since 530 claims encompass the claimed limitations.

5. Claims 31-34 and 39-43, 46 and 49-56 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 13-16 of U.S. Patent No. 5,997,848. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in said patent and instant claims recite the same insulin compositions. The patented claims however, are drawn to a method of delivering insulin. In the dependent patented claim 5, the insulin is present in an amount of 5 to 99 % and the particles and the particles are less than 10 microns in diameter. The carrier material is either a carbohydrate, organic salt or an amino acid. The patented claims are generic with respect to the amount of

insulin and the carrier and therefore, instant claims are anticipated over the claims of said patent.

Applicant indicates the willingness to file a terminal disclaimer. The rejection is maintained in abeyance.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore, Ph.D/
Primary Examiner, Art Unit 1612

GSK